

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TALECRIS BIOTHERAPEUTICS, INC., and
BAYER HEALTHCARE LLC,

Plaintiffs,

v.

BAXTER INTERNATIONAL INC., and
BAXTER HEALTHCARE CORPORATION,

Defendants.

BAXTER HEALTHCARE CORPORATION

Counterclaimant,

v.

TALECRIS BIOTHERAPEUTICS, INC., and
BAYER HEALTHCARE LLC,

Counterclaim Defendants.

C.A. No. 05-349-GMS

Jury Trial Demanded

**PLAINTIFFS' BRIEF IN OPPOSITION TO DEFENDANTS' MOTION FOR
LEAVE TO FILE AMENDED ANSWER AND COUNTERCLAIM**

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TABLE OF CONTENTS

	PAGE
I. INTRODUCTION	1
II. SUMMARY OF ARGUMENT	3
III. STATEMENT OF FACTS	4
IV. LEGAL STANDARDS	6
A. Rule 16 Requires a Showing of Good Faith to Modify the Scheduling Order.	6
B. The Court May Also Deny a Motion to Amend under Rule 15 on the Basis of Undue Delay, Prejudice, or Futility	7
V. ARGUMENT	8
A. Defendants Have Failed to Make the Requisite Showing of Good Cause to Modify the Scheduling Order Set Forth in Rule 16.	8
B. Defendants’ Motion to Amend Should Also Be Denied Under Rule 15 on the Basis of Undue Delay and Prejudice.	8
C. Defendants’ Motion to Amend Should Be Denied Under Rule 15 Because Defendants’ Proposed Amendment Is Futile.....	9
1. Dr. Alonso Disclosed the Most Material Prior Art References.	9
2. Dr. Alonso Explicitly Disclosed the Prior Use of Gamimune® N in the ‘191 Patent.	10
3. Defendants’ Data Allegations Are Equally Futile	12
VI. CONCLUSION.....	13

TABLE OF AUTHORITIES

	PAGE
Cases	
<i>Bayer AG v. Housey Pharms., Inc.</i> , 128 Fed. Appx. 767 (Fed. Cir. 2005).....	11
<i>Deghand v. Wal-Mart Stores, Inc.</i> , 904 F Supp. 1218 (D. Kan. 1995).....	7
<i>Dimensional Commc'ns, Inc. v. Oz Optics, Ltd.</i> , 148 Fed. Appx. 82, (3d Cir. 2005), <i>cert. denied</i> , 2006 U.S. LEXIS 1698 (2006).....	6
<i>E. Minerals & Chems. Co. v. Mahan</i> , 225 F.3d 330 (3d Cir. 2000)	6
<i>Foman v. Davis</i> , 371 U.S. 178 (1962).....	7
<i>Globespanvirata, Inc. v. Texas Instr. Inc.</i> , No. 03-2854, 2005 WL 1638136 (D.N.J. July 12, 2005)	7
<i>Gonzalez v. Comcast Corp.</i> , No. 03-445, 2004 U.S. Dist. (D. Del. Aug. 25, 2004)	7
<i>Halliburton Co. v. Schlumberger Tech. Corp.</i> , 925 F.2d 1435 (Fed. Cir. 1991)	10
<i>Hutchins v. United Parcels, Inc.</i> , No.01-1462, 2005 WL 1793695 (D.N.J. July 26, 2005)	6
<i>Katzenmoyer v. City of Reading</i> , 158 F. Supp. 2d 491 (E.D. Pa. 2001).....	7
<i>Koplove v. Ford Motor Co.</i> , 795 F.2d 15 (3d Cir. 1986)	7
<i>Lorenz v. CSX Corp.</i> , 1 F.3d 1406 (3d Cir. 1993)	7
<i>Rose Hall, Ltd. v. Chase Manhattan Overseas Banking Corp.</i> , 93 F.R.D. 858 (D. Del. 1982)	7
<i>Ruiz v. A.B. Chance Co.</i> , 234 F.3d 654 (Fed. Cir. 2000)	11

<i>S&W Enters. v. Southtrust Bank of Alabama, N.A.</i> , 315 F.3d 533 (5th Cir. 2003)	6
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<i>SanDisk Corp. v. Memorex Prods., Inc.</i> , 415 F.3d 1278 (Fed. Cir. 2005)	12
--	----

<i>Turner v. Schering-Plough Corp.</i> , 901 F.2d 335 (3d Cir. 1990)	7
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Statutes

15 U.S.C. §1051(a)(1).....	11
----------------------------	----

Rules

37 C.F.R. § 1.56.....	9
-----------------------	---

Fed. R. Civ. P. 15(a)	7
-----------------------------	---

Fed. R. Civ. P. 16.....	7
-------------------------	---

Fed. R. Civ. P. 16(b)	6
-----------------------------	---

Fed. R. Civ. P. 9(b)	9
----------------------------	---

I. INTRODUCTION

Plaintiffs and Counterclaim Defendants Talecris Biotherapeutics, Inc. (“Talecris”) and Bayer Healthcare LLC (“Bayer”) (collectively, “Plaintiffs”) filed this case for infringement of U.S. Patent No. 6,686,191 (the “’191 patent”) against Defendants Baxter International Inc. and Baxter Healthcare Corporation (collectively, “Defendants”) on June 1, 2005. Defendants’ Answer to Complaint and Counterclaim for Declaratory Judgment, filed on August 31, 2005, includes four affirmative defenses and seeks a declaratory judgment of noninfringement and invalidity of the ‘191 patent. Defendants did not include an affirmative defense of inequitable conduct, nor did they seek a declaratory judgment of unenforceability of the ‘191 patent.

The deadline for amending pleadings was May 5, 2006. This date was stipulated by the parties, and it was included in the Scheduling Order. D.I. 17. The Scheduling Order also included a fact discovery cut-off date entered at the Defendants’ insistence. D.I. 16, p. 4, 1.22-p.6, 1.22. Plaintiffs timely amended their Complaint by the May 5, 2006 deadline, and Defendants timely filed an Answer to Amended and Supplemental Complaint and Counterclaim for Declaratory Judgment on May 30, 2006. However, at this time, Defendants again did not allege inequitable conduct. Now, six months after the agreed deadline for amending pleadings prescribed in the Scheduling Order, and six weeks after the close of fact discovery, a date urged by Defendants, Defendants have belatedly filed a Motion to Amend their Answer and Counterclaims to include for the first time a claim of inequitable conduct.

In their Motion to Amend (hereinafter “Defendants’ Motion” or the “Motion”) Defendants fail to address the proper legal standard for their Motion, that is, they fail to

meet the requisite showing of “good cause” under Federal Rule of Civil Procedure 16 to seek leave to amend after the time set forth in the Scheduling Order. For this reason alone, the Court should deny Defendants’ Motion.

Defendants also unduly delayed in seeking leave to amend and, as a result, Plaintiffs will be prejudiced if Defendants are allowed to amend at this time. Their delay cannot be justifiably excused. Many of the facts contained in Defendants’ proposed amendments were known to Defendants far in advance of the May 5, 2006 deadline and well before the close of fact discovery. For example, counsel for Defendants represented Bayer in 1992-93 and worked directly with James Giblin, an in-house attorney for Bayer. During this same time frame, a patent naming Grace Tsay as an inventor, who worked for Bayer, was being prosecuted by Mr. Giblin. U.S. Patent No. 5,256,771 (the “Tsay patent”) issued on October 26, 1993 and is one of the bases for Defendants’ inequitable conduct charge. Defendants long ago had to know of the patent and the fact that it was not cited in the prosecution of the ’191 patent in suit. These facts were publicly available. Counsel for Defendants also questioned Mr. Giblin about the Tsay patent in a deposition on August 1, 2006, but no amendment was sought at that time. Grace Tsay is a third party who also was deposed in this case. Defendants remained silent about alleged inequitable conduct until after Ms. Tsay’s deposition in this case. Defendants’ delay is prejudicial since Ms. Tsay’s deposition has been completed.

Defendants also had to know prior to the filing of this case (1) that Gamimune® N was being publicly sold in the United States since they were a primary competitor of Bayer and (2) that Gamimune® N was disclosed in the specification of the ’191 patent. Yet, no inequitable conduct charge was brought on this basis until November 2006.

Adding an entirely new claim to this case after the close of fact discovery as the parties enter the claim construction and expert discovery phase of this case is prejudicial to Plaintiffs.¹

For these reasons and those set forth below, leave to amend should be denied.

II. SUMMARY OF ARGUMENT

The Scheduling Order's deadline for Defendants to amend their answer and counterclaims passed six months ago on May 5, 2006. On May 30, 2006, Defendants had the opportunity to amend their answer and counterclaims in response to Plaintiffs' Amended and Supplemental Complaint, yet they chose not to do so. Defendants should not be permitted to add an entirely new (and futile) claim of unenforceability for alleged inequitable conduct after the close of fact discovery.

Defendants have completely ignored their obligation under Federal Rule of Civil Procedure 16(b) to establish "good cause" to modify the Scheduling Order. D.I. 17. Evidence upon which Defendants rely was available to them at least as early as October 2005. Further, Defendants' excuse that they needed to wait to depose the inventor of the '191 patent, Dr. William Alonso, before bringing such claims is disingenuous. They never even asked Dr. Alonso in his deposition about the purportedly invalidating pieces of prior art which forms one of the bases for their claim. Defendants' proposed amendment also falls short of the requirements of Federal Rule of Civil Procedure 9(b). They do not name with specificity the attorney or attorneys they are accusing of inequitable conduct. Defendants also had knowledge of many of the alleged facts on

¹ The claim construction hearing is scheduled for December 14, 2006 and opening expert reports are due on January 10, 2007.

which they rely in their proposed amendment, in some instances even prior to the filing of this case. They unduly delayed in seeking to amend.

The proposed amendment is also futile. Defendants must meet a heavy burden of clear and convincing evidence. They cannot do so.

Given Defendants' failure to meet the standards of Rule 16, their undue delay, the futility of their defective amendments, and the prejudice to Plaintiffs should Defendants be allowed to amend their pleadings at this late date, Plaintiffs' respectfully request that the Court deny Defendants' Motion.

III. STATEMENT OF FACTS

Plaintiffs filed their Complaint on June 1, 2005. D.I. 1. On August 31, 2005, Defendants filed their Answer and Counterclaim for Declaratory Judgment which includes four affirmative defenses and seeks a declaratory judgment of noninfringement and invalidity of the '191 patent. D.I. 5. Defendants did not include any affirmative defense of inequitable conduct, nor did they seek declaratory judgment of unenforceability of the '191 patent.

The deadline in the Scheduling Order for amending pleadings was May 5, 2006. D.I. 17. Plaintiffs timely amended their Complaint on May 5, 2006. On May 30, 2006, Defendants filed their Answer to Amended and Supplemental Complaint and Counterclaim for Declaratory Judgment. D.I. 28. Defendants again did not allege inequitable conduct.

Plaintiffs moved to disqualify Defendants' counsel on August 25, 2006 after learning that Defendants' counsel had previously filed suit as Bayer's counsel in a suit to enforce U.S. Patent No. 4,396,608 ("the Tenold patent"), a case involving related subject

matter. D.I. 76, *see also* D.I. 107. This motion is *sub judice*. Defendants' counsel had thus previously represented Bayer in a confidential relationship at the time when a patent naming Grace Tsay as an inventor, U.S. Patent No. 5,256,771, which issued on October 26, 1993, was being prosecuted and which listed Mr. Giblin as the prosecuting attorney. Defendants' attorney worked closely with Mr. Giblin in the Tenold patent case. Significantly, the facts relating to commercialization of Gamimune® N, one of the bases for Defendants' Amendment, were directly at issue in the Tenold case as more fully described in our disqualification submissions. See D.I. 76; D.I. 107, Exs. 15-16.

Fact discovery closed on September 29, 2006. It was not until November 6, 2006, six months after the deadline for amending pleadings, that Defendants filed a motion to amend their Answer and Counterclaims to include for the first time an entirely new claim of inequitable conduct.

Prior to the instant suit, on October 1, 2004, Defendants filed an opposition to the European counterpart of the '191 patent, EP 0 764 447. In their publicly available statement of opposition, Defendants argued that the Tenold patent, the subject of the 1992-93 litigation, can be taken as the closest prior art. Ex. A, p. 3; *see also*, Ex. B, pp. 3-4. On October 10, 2005, four months after Plaintiffs filed the instant suit, Defendants introduced Ng, *et al.*, "Process-Scale Purification of Immunoglobulin M Concentrate", *Vox. Sang.*, 65:81-86 (1993) (the "Ng reference") as a prior art reference in the European opposition proceedings. Ex. B, p. 11. On August 3, 2006, Defendants argued in Europe that the Ng reference can be taken as the closest prior art reference. Ex. C, p. 4.

On August 1, 2006, Defendants deposed Mr. Giblin, who prosecuted the '191 patent in suit. Counsel for Defendants questioned Mr. Giblin on the Tsay patent which

forms one of the bases for Defendants' inequitable conduct charge. Yet, Defendants did not seek to timely amend its pleading at this time. Defendants thereafter never even asked Dr. Alonso in his deposition about either the Tsay patent or the Ng reference, despite asserting both references as a basis for inequitable conduct. D.I. 165, Ex. A, p. 11..

IV. LEGAL STANDARDS

A. Rule 16 Requires a Showing of Good Faith to Modify the Scheduling Order.

Rule 16(b) of the Federal Rules of Civil Procedure governs amendment of pleadings once a scheduling order has been entered. *E. Minerals & Chems. Co. v. Mahan*, 225 F.3d 330, 340 (3d Cir. 2000) (affirming denial of leave to amend where district court concluded that it need not examine movant's Rule 15(a) argument absent a showing of good cause under Rule 16(b)); *S&W Enters. v. Southtrust Bank of Alabama, N.A.*, 315 F.3d 533, 535-36 (5th Cir. 2003) ("[T]he presence of a scheduling order renders the Rule 15 inquiry secondary.") (cited with approval in this circuit by *Hutchins v. United Parcels, Inc.*, No.01-1462, 2005 WL 1793695 (D.N.J. July 26, 2005)); *see also Dimensional Commc'ns, Inc. v. Oz Optics, Ltd.*, 148 Fed. Appx. 82, 85, (3d Cir. 2005) (specifically rejecting contention that "the Third Circuit has not adopted a 'good cause' requirement in determining the propriety of a motion to amend a pleading after the deadline has elapsed"), *cert. denied*, 2006 U.S. LEXIS 1698 (2006). Rule 16 provides that a pretrial scheduling order "shall not be modified except upon a showing of *good cause* and by leave of the district court" Fed. R. Civ. P. 16(b) (emphasis added). "[S]cheduling orders are the heart of the case management', and if they can be flouted [by] counsel . . . 'their utility will be severely impaired'." *Turner v. Schering-Plough*

Corp., 901 F.2d 335, 341 (3d Cir. 1990) (quoting *Koplove v. Ford Motor Co.*, 795 F.2d 15, 18 (3d Cir. 1986)).

“Good cause” under Rule 16 means that the moving party must show that it is unable to operate within scheduling deadlines despite diligent effort to comply. *Gonzalez v. Comcast Corp.*, No. 03-445, 2004 U.S. Dist. LEXIS 17896, at *2-3. (D. Del. Aug. 25, 2004); *see also* Fed. R. Civ. P. 16 advisory committee’s note (“[T]he court may modify the schedule on a showing of good cause if [the deadlines] cannot be reasonably met despite the diligence of the party seeking the extension.”). Further, the absence of prejudice to the nonmovant is *not* a consideration under the good cause standard. *Deghand v. Wal-Mart Stores, Inc.*, 904 F. Supp. 1218, 1221 (D. Kan. 1995), *cited with approval in Globespanvirata, Inc. v. Texas Instr. Inc.*, No. 03-2854, 2005 WL 1638136 (D.N.J. July 12, 2005).

B. The Court May Also Deny a Motion to Amend under Rule 15 on the Basis of Undue Delay, Prejudice, or Futility

Under Rule 15 of the Federal Rules of Civil Procedure, it is within the discretion of the Court to deny leave to amend where a party will be substantially or unduly prejudiced or where the court finds bad faith, dilatory motives, or futility. *Lorenz v. CSX Corp.*, 1 F.3d 1406, 1413-14 (3d Cir. 1993) (citing *Foman v. Davis*, 371 U.S. 178, 182 (1962)). Defendants bear the burden to prove that “justice requires” that leave to amend be granted, including the burden of explaining the reasons for delay. Fed. R. Civ. P. 15(a); *Rose Hall, Ltd. v. Chase Manhattan Overseas Banking Corp.*, 93 F.R.D. 858, 865 (D. Del. 1982); *Katzenmoyer v. City of Reading*, 158 F. Supp. 2d 491, 497 (E.D. Pa. 2001) (“An applicant seeking leave to amend a pleading has the burden of showing that justice requires the amendment.”).

V. ARGUMENT

A. Defendants Have Failed to Make the Requisite Showing of Good Cause to Modify the Scheduling Order Set Forth in Rule 16.

Defendants completely failed to address the “good cause” standard of Rule 16(b) in their Opening Brief, despite the Third Circuit’s mandate that such a showing be made by a party seeking leave to amend after the date set forth in the Scheduling Order. Their brief is totally silent on this dispositive point. Defendants long ago knew of facts on which they now base their inequitable conduct claim, such as the Tsay patent and Gamimmune ® N, which was directly at issue in the 1992 lawsuit filed by Defendants’ counsel on behalf of Bayer. Defendants now assert these facts directly against Plaintiffs. For this reason alone, Defendants’ Motion should be denied.

B. Defendants’ Motion to Amend Should Also Be Denied Under Rule 15 on the Basis of Undue Delay and Prejudice.

Defendants unduly delayed in seeking leave to amend without showing any good cause. As a result, Plaintiffs will be prejudiced if Defendants are allowed to amend their answer and counterclaims. Facts contained in Defendants’ proposed amendment were known to Defendants far in advance of the May 5, 2006 deadline and, at the very least, well before the close of fact discovery in this case. Yet, Defendants waited until six months after the date set forth in the Scheduling Order and four weeks after the close of fact discovery to assert their claims of inequitable conduct. Adding a new claim to this case as the parties enter the claim construction and expert discovery phase of this case is prejudicial to Plaintiffs, particularly when both Grace Tsay and Paul Ng, third party witnesses, have already been deposed on their activities.

Further, Defendants' oft-repeated refrain that they needed to wait until they deposed Dr. Alonso, the inventor of the '191 patent, before they amended the pleadings, is frivolous – they never even asked Dr. Alonso about the prior art they now claim is a basis for inequitable conduct during his deposition.

Finally, Defendants have not alleged with specificity who they are even accusing of inequitable conduct – referring only to “Bayer” and “Bayer attorneys”. Rule 9 of the Federal Rules of Civil Procedure requires that Defendants plead inequitable conduct with specificity. Fed. R. Civ. P. 9(b). And rules and regulations of the Patent Office require that inequitable conduct be asserted against **individuals** who have a duty of disclosure before the Patent Office. It is well-settled that inequitable conduct is committed by individuals, not companies. *See* 37 C.F.R. § 1.56 (“*Each individual* associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the [PTO], which includes a duty to disclose to the Office *all information known to that individual* to be material to patentability”) (emphasis added). By failing to specify who they are accusing of inequitable conduct, Defendants' claims are fatally defective. Moreover, Plaintiffs cannot properly defend against claims of inequitable conduct without at least knowledge of who is being accused.

C. Defendants' Motion to Amend Should Be Denied Under Rule 15 Because Defendants' Proposed Amendment Is Futile.

Defendants' claim of inequitable conduct is fatally defective, and thus the proposed amendment is futile.

1. Dr. Alonso Disclosed the Most Material Prior Art References.

Defendants allege that Dr. Alonso and the unidentified “attorneys” prosecuting the '191 patent failed to disclose to the Patent Office two references in the possession of

Bayer and/or its prosecuting attorneys: (1) the Tsay patent, and (2) the Ng reference. *See* D.I. 165, Ex. A, p. 11. However, these references are not material for the purposes of inequitable conduct.

The Tenold patent is, in Defendants' own words, "the closest item of prior art." *Id.* Ex. A, p. 3; *see also* Ex. B, pp. 3-4. On October 1, 2004, Defendants clearly stated that the Tenold patent is the closest prior art in its opposition to European counterpart of the '191 patent. It was not until after Plaintiffs had filed the instant suit that Defendants introduced the Ng reference for the first time in the opposition proceedings on October 10, 2005. Ex. B, p. 11. Another year had almost passed before Defendants suddenly claimed Ng was the closest prior art reference in the opposition proceedings. Ex. C, p. 4.²

A reference need not be disclosed if it is less material than other references already disclosed. *Halliburton Co. v. Schlumberger Tech. Corp.*, 925 F.2d 1435, 1440 (Fed. Cir. 1991) (reversing district court's clearly erroneous finding of inequitable conduct because undisclosed prior art was less material than disclosed prior art). The failure to cite the Tsay patent and the Ng references is therefore not a proper basis for inequitable conduct because, as Defendants have admitted in Europe, the Tenold patent is the most pertinent art. Thus, Defendants' inequitable conduct allegation is *per se* futile.

2. Dr. Alonso Explicitly Disclosed the Prior Use of Gamimune® N in the '191 Patent.

Defendants allege that Dr. Alonso and Bayer engaged in inequitable conduct by not disclosing Gamimune® N, which is supposedly claimed by Claim 23 of the '191

² Defendants' reliance on the Ng reference and the Tsay patent is particularly suspect given that its counsel in this case represented Bayer in 1992-93 and had access to the work of Tsay, Ng, and others in the course of that confidential relationship. This prior representation is the basis for Plaintiffs' motion to disqualify Defendants' current counsel. *See* D.I. 76; D.I. 107. This motion is *sub judice*.

patent. *See* D.I. 165, Ex. A, p. 12. Defendants fail to point out column 5, lines 36-40 of the '191 patent, where Gamimune® N 10% is explicitly disclosed. *See* D.I. 167, Ex. 1. This clear language is more than sufficient disclosure. As the patent examiner and the public know, the trademark symbol ® indicates that a product is being sold in commerce – indeed, it is a threshold requirement for trademark registration under the Lanham Act. 15 U.S.C. §1051(a)(1). The language of prior use is a sufficient disclosure. *See, e.g., Ruiz v. A.B. Chance Co.*, 234 F.3d 654 (Fed. Cir. 2000). Furthermore, the patent specification incorporates the Tenold patent by reference.

In *Ruiz*, the claims at issue disclose an apparatus and method for raising and supporting a structure such as a building foundation using push piers and metal brackets. *Id.* at 661. The prior art included a method using screw anchors with concrete haunches as an underpinning solution. *Id.* The specification disclosed “earth anchor language” and a “reference to a piling and other materials in the patent file wrapper history.” *Id.* at 670. The infringer alleged that the patentee engaged in inequitable conduct by not disclosing the method more precisely. *Id.* The district court held that the disclosures were “sufficient to disclose the...prior art,” and the Federal Circuit affirmed.

Similarly, in an appeal from a decision of this Court in favor of Bayer, the accused infringer, the Federal Circuit reversed and vacated a finding of inequitable conduct because the information in question (prior art) was cited in the patent specification. *See Bayer AG v. Housey Pharms., Inc.*, 128 Fed. Appx. 767, 770 (Fed. Cir. 2005).

For the same reason, the '191 specification's explicit disclosure of Gamimune® N 10% is more than sufficient disclosure of prior use. Moreover, the prosecution history

and all of the facts relating to Gamimune® N 10% have been publicly available, and all have been available to Defendants for years. Hence, Defendants' allegation of inequitable conduct is futile and untimely.

3. Defendants' Data Allegations Are Equally Futile

Defendants allege that Dr. Alonso intentionally omitted highly material data with the intent to deceive the PTO. D.I. 166, pp. 9-12. Specifically, among other things, Defendants allege Dr. Alonso and "Bayer" failed to submit other data which purportedly showed that ACA levels did not always elevate to "unacceptable levels", a term which Defendants seek to read into the claimed invention and which Defendants acknowledge is the subject of ongoing claim construction briefing. Defendants also allege Dr. Alonso failed to disclose pH 5.8 data. D.I. 165, Ex. A, p. 15-17.

Defendants pH 5.8 data claim fails because the pH 5.8 data is cited in the specification. *See* D.I. 167, Ex. 1, col. 9, ll.24-37, Table 7. Because the pH 5.8 data were disclosed in the specification, Defendants' inequitable conduct allegation cannot stand.

Similarly, Defendants' allegations relating to the TNBP/Tween data (D.I. 165, Ex. A, p. 14-15), while devoid of merit on numerous other grounds, is facially defective without more because, as Defendants state, it depends on Defendants' faulty claim construction that the claimed invention requires that ACA levels always rise to levels that Defendants argue are "unacceptable". It cannot be inequitable conduct when the accusation depends on reading a limitation into the claim in violation of Federal Circuit law. *See, SanDisk Corp. v. Memorex Prods., Inc.*, 415 F.3d 1278, 1286 (Fed. Cir. 2005) ("References to a preferred embodiment, such as those often present in a specification, are not claim limitations") (citations omitted).

VI. CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that the Court deny Defendants' Motion for Leave to File Amended Answer and Counterclaim.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Jeffrey B. Bove, hereby certify that on November 16, 2006, the within document was filed with the Clerk of Court using CM/ECF which will send notification of such filings(s) to the following; that the document was served on the following counsel as indicated; and that the document is available for viewing and downloading from CM/ECF.

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